

Board
decision
C7

28. The device of claim 1 further comprising an agent reservoir disposed on the ~~[body surface distal side]~~ second surface of the member.

Please insert new claim 30.

AS

--30. A device for introducing or withdrawing an agent through a body surface, comprising:

a member having a body surface proximal side, a body surface distal side and a plurality of protrusions extending from said body surface proximal side; said member further having at least one hole through the member.

a connecting medium capable of storing the agent therein or passing the agent therethrough on at least a portion of the body surface proximal side of the member; and

a sampling device connected to the body surface distal side, the sampling device selected from the group consisting of a reverse osmosis device, an electrotransport device, a passive device and an osmotic device.--

REMARKS

Currently pending are claims 1-8, 10-21, and 23-29. No claims have been cancelled and claim 30 has been added by the present amendment. A clean set of all pending claims is attached hereto as Appendix A.

Applicant's wish to thank Examiner Rodriguez for conducting a phone interview on 26 October 2000, a summary of which was dated 02 November 2000.

A. Rejection based upon 35 U.S.C. § 102 in view of Lee, EPO 0 429 842

The examiner asserts that the Lee reference, EPO 0 429 842 anticipates the present invention. However, Applicant's wish to point out that the Drug Reservoir 3 of Lee is disposed on the surface of Skin Needle Support 5 that is distal to the body. Applicant's claims clearly provide for the connecting medium to be disposed on the surface of Applicants' Member 6 that is proximal to the body, i.e. the first surface as provided in the independent claims and shown as reference number 48 on page 6 of the specification.

In order to provide greater clarity, the Applicants have amended the claims to make reference to a first and second surface of the member located on the body surface distal side and the body surface proximal side of the member. In response to the Examiner's comments made in response to a set of proposed claims faxed to the Examiner, Applicant's have included language which positively recites a proximal and distal side of the member and then recites a first and second surface located respectively on the proximal and distal side of the member.

Because all elements of the Applicant's claims are not disclosed in the Lee prior art reference, that reference cannot be anticipatory. Applicant's respectfully request the withdrawal of the § 102 rejection.

CONCLUSION

As all objections put forth by the examiner have been addressed by the amendments to the claims provided herein and by the remarks provided, Applicants respectfully assert that the application is in condition for allowance, notice of which is earnestly solicited.

Respectfully submitted,

Dated: 16 November 2000

By: Owen J. Bates

Owen J. Bates
Registration No. 40,346

ALZA Corporation
1900 Charleston Road
(P.O. Box 7210)
Mountain View, CA 94043
Telephone: (650) 564-7867 Fax: (650) 564-2195

Appendix A

1. (twice amended) A device for introducing or withdrawing an agent through a body surface, comprising:

a member having a body surface proximal side and a body surface distal side;

said member further having a first surface on the body surface proximal side of the member, a second surface on the body surface distal side of the member and a plurality of protrusions extending from the first surface and extending towards the body surface; and

a connecting medium capable of storing the agent therein or passing the agent therethrough disposed on at least a portion of the first surface of the member.

2. The device of Claim 1 wherein the member has an opening therethrough.
3. The device of Claim 2 wherein the connecting medium extends across the opening.
4. The device of Claim 2 wherein the connecting medium extends through the opening.
5. The device of Claim 2 wherein the connecting medium is in the opening.
6. The device of Claim 1 wherein the connecting medium is in the range of about 10 micrometers to about 100 micrometers thick.
7. The device of Claim 1 wherein the connecting medium is about 50 micrometers thick.
8. The device of Claim 1 wherein the connecting medium comprises a hydrogel.

10. The device of Claim 1 wherein the connecting medium comprises a form selected from the group consisting of a gel, a solid and a powder.
11. The device of Claim 1 wherein the connecting medium further comprises a matrix material.
12. The device of Claim 1 wherein the protrusions comprise blades.
13. The device of Claim 12 wherein at least one of the plurality of blades comprises means for anchoring the device to the body surface.
14. (twice amended) The device of claim 2 further comprising an agent delivery device connected to the second surface of the member, the agent delivery device selected from the group consisting of an electrotransport device, a passive device, an osmotic device, and a pressure driven device.
15. The device of claim 14 wherein the agent delivery device is capable of delivering at least one agent selected from the group consisting of an oligonucleotide drug, a polynucleotide drug, a gene, a polypeptide and a protein.
16. (twice amended) The device of claim 1 further comprising a sampling device connected to the second surface of the member, the sampling device selected from the group consisting of a reverse electrotransport device, a passive device, and an osmotic device.
17. (Amended) The device of claim 16 wherein the sampling device is capable of sampling agents selected from the group consisting of body electrolytes, illicit drugs, and glucose.

18. (twice amended) A device for introducing or withdrawing an agent through a body surface, the device comprising:

a member having a body surface proximal side and a body surface distal side;
said member further having a first surface on the body surface proximal side of the member; a second surface on the body surface distal side of the member; a plurality of protrusions extending from the first surface and extending towards the body surface and at least one opening through the member; and

a connecting medium capable of storing the agent therein or passing the agent therethrough, the connecting medium being disposed on at least a portion of the first surface and further disposed in the at least one opening.

19. (twice amended) The device of Claim 18 wherein the connecting medium is disposed on a portion of the first surface.

20. (Amended) The device of claim 18 wherein the connecting medium is capable of storing an agent that is selected from the group consisting of an oligonucleotide drug, a polynucleotide drug, a gene, a polypeptide, and a protein.

21. The device of claim 18 wherein the connecting medium comprises a hydrogel.

23. (twice amended) A method for introducing an agent through a body surface, comprising the steps of:

providing a member having a body surface proximal side, a body surface distal side, a first surface on the body surface proximal side of the member and a second

surface on the body surface distal side of the member; said member having a plurality of protrusions extending from the first surface and extending towards the body surface and a connecting medium disposed on at least a portion of the first surface;

introducing the agent in the connecting medium;

piercing the body surface with the plurality of protrusions extending from the first surface of the member;

contacting the body surface with the connecting medium; and

passing the agent through the body surface.

24. The method of Claim 23 wherein the passing step comprises:
administering the agent by a method selected from the group consisting of electrotransport, passive delivery, osmosis, and pressure.

25. (amended twice) The method of claim 26 wherein the withdrawing step comprises:

withdrawing the agent by a method selected from the group consisting of reverse electrotransport, passive sampling, and osmosis.

26. A method for withdrawing an agent through a body surface, comprising the steps of:

piercing the body surface with a plurality of protrusions extending from a body surface proximal side of a member having a connecting medium capable of passing the agent therethrough, the connecting medium disposed on at least a portion of the body surface proximal side;

contacting the body surface with the connecting medium; and

withdrawing the agent through the body surface.

27. A device for introducing or withdrawing an agent through a body surface, comprising:

a member having a body surface proximal side, a body surface distal side and a plurality of protrusions extending from said body surface proximal side;

a connecting medium capable of storing the agent therein or passing the agent therethrough on at least a portion of the body surface proximal side of the member; and

a sampling device connected to the body surface distal side, the sampling device selected from the group consisting of a reverse osmosis device, an electrotransport device, a passive device and an osmotic device.

28. The device of claim 1 further comprising an agent reservoir disposed on the second surface of the member.

29. The device of claim 28 where said agent reservoir is an element of an agent delivery apparatus selected from a group consisting of an electrotransport device, a passive device, an osmotic device and a pressure driven device.

30. A device for introducing or withdrawing an agent through a body surface, comprising:

a member having a body surface proximal side, a body surface distal side and a plurality of protrusions extending from said body surface proximal side; said member further having at least one hole through the member.

a connecting medium capable of storing the agent therein or passing the agent therethrough on at least a portion of the body surface proximal side of the member; and

a sampling device connected to the body surface distal side, the sampling device selected from the group consisting of a reverse osmosis device, an electrotransport device, a passive device and an osmotic device.